# THE FUTURE OF GENERIC MEDICINE BUSINESS MODELS IN BRAZIL AND PHARMACEUTICAL INDUSTRIES[1]

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## 1. INTRODUCTION

The pharmaceutical industry as we know it - in the form of a corporation that takes on large proportions, has existed since the end of the 19th century. According to **Drews (2000)**, industrial and large-scale research for medicines to fight diseases does not exceed much more than a century, having its main discoveries since the 1930s, with the advent of penicillin by Alexander Fleming. Among the so-called niches in the pharmaceutical market, we find diseases of greater complexity and less incidence. As an example, we have rheumatoid arthritis (chronic inflammatory disease) that affects between 0.5% and 1% of the population, according to **Almeida (2014)**. Also, **Mega et al (2015)** demonstrate the existing complexity for the creation of a PCDT (clinical protocol and therapeutic guidelines) in SUS. It is noticed that even within therapeutic areas that comprise a smaller portion of the population, the patient's journey begins with medicines of greater offer/lower cost and according to the evolution of the intensity of the same disease, the patient is presented with greater technology, higher cost and less supply.

### 1.1. Question and Objectives

- What is the probable scenario and how the pharmaceutical industry will be impacted by generic medicines, until the year 2030?

This article seeks to organize different international and national studies, and within the

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international section there is a division between productions aimed at the market, the regulatory issue or public policies, in addition to standards, which stand out among the topics most addressed by international studies of according to a survey on the Web of Science). In order to compose the 2030 scenario, the study counted on the contribution of 10 pharmaceutical specialists (executives and academics).

### 1.2 Justification

The way in which the pharmaceutical industry will continue to deal with the perspective brought by generic medicines and biosimilars is not yet clearly outlined and shall impact companies, the government health policies and patients.

## 2. METHODS

Following the methodology of **Strand et al (2015)** for selection of specialists, the CV of the participants in the Delphi process was analyzed considering their academic and business history, as well as their contributions to the theme of the health, pharmaceutical and generics market/policies.

The Delphi method, according to **Gordon (1994)**, consists of the exposure of a current base scenario and its historical attributes that justified this situation. Then, the experts on the topic addressed are submitted to a questionnaire/statement and expose their perspective on the subject on the future. The data are consolidated, and the same specialists are submitted to new rounds until there is a convergent scenario in which the majority or all of the specialists agree that it will be the best representation of a projection for the future. **Sekayi and Kennedy (2017)** revealed that 2 to 4 interactions are sufficient to obtain a converging scenario.

The organization and structuring of themes and questions takes place according to table 1:

**Table 1.** Themes, concepts and background for Delphi scenario:

| Theme | Concept | National Background | International Background |
|---|---|---|---|
| **1. National pharmaceutical industry of generics** | Comprised only by the Brazilian pharmaceutical industries that are limited to operate in the generic market | • Quental et al (2007)<br>• Isse (2011) | • Reiffen (2005)<br>• Fatokun (2013) |
| **2. Local pharmaceutical industry** | Comprised of national and international generic and reference/research medicine industries installed in Brazilian territory | • Nishijima (2008)<br>• Nishijima et al (2014)<br>• Paranhos et al (2020) | • Guler and Nerkar (2012)<br>• Thomas (2004)<br>• Tannoury and Attieh (2017) |
| **3. Biological, biosimilar medicines and new technologies** | It comprises borderline/high-cost medicines and the incorporation of technologies (CONITEC). | • Torres et al (2017)<br>• Pagani (2019) | • Mellstedt et al (2008)<br>• Berkowitz et al (2012)<br>• Kurki et al (2017)<br>• Cohen (2018) |
| **4. Market regulatory agencies** | Comprises the regulatory agencies of the Brazilian pharmaceutical market, ANS, ANVISA, SUS etc. | • Lima (2017)<br>• Schulman (2020)<br>• Couto et al (2021) | • Stafford (2008)<br>• Baden et al (2020) |
| **5. Brazilian public health** | Understands the opinions of experts on the SUS, the Ministry of Health, the performance of the executive (presidency of the republic) and legislative (chamber of deputies and senate) powers in relation to the topic of health, its laws, its incentives and investments | • Machado et al (2007)<br>• Silva et al (2011)<br>• Paim (2018)<br>• Bahia (2018)<br>• Malta et al (2019) | • Westphal (2007)<br>• Cohn (2011) |

Source: prepared by the authors.

## 3. RESULTS AND DISCUSSION

In order to determine the results of the Delphi method in order to send a consolidated scenario of opinions, it was decided to identify the experts' responses among 3 groups (favorable, unfavorable and neutral) in relation to each of the proposed questions.

Following the structure proposed above, under which the experts' expectations were gathered, the details of the scenario are set out below.

The results obtained in the converging Delphi scenario can be found in Table 2.

**Table 2**. Converging scenario for generics in Brazil, obtained from experts opinions


| | Theme | Measure | Result | Pros | Cons | Neutral | TOTAL Participants |
|---|---|---|---|---|---|---|---|
| 1 | Research industry involv. on Generics | *Multinational pharmaceutical interest on dev. generics* | -9 | 0 | -9 | 1 | 10 |
| 2 | Brazilian ind. Market share | *Growth of the brazilian generics market share* | 1 | 4 | -3 | 3 | 10 |
| 3 | Generic drugs share/total | *Generic market share drugs growth in relation to the total market* | 8 | 8 | 0 | 2 | 10 |
| 4 | Pharma profits/margins | *Evolution of the profit margin Pharmaceutical industry* | -5 | 0 | -5 | 5 | 10 |
| 5 | Success Biosimilars = Generics? | *Success of biosimilars in relation to generics* | -10 | 0 | -10 | 0 | 10 |
| 6 | SUS position x Biosimilars | *SUS behavior in relation to generics* | 8 | 8 | 0 | 2 | 10 |
| 7 | Private market position | *Position of ANS and private agents in relation to generics* | 5 | 5 | 0 | 5 | 10 |
| 8 | Regulatory change/ANVISA | *Regulatory positioning/ANVISA about generics* | -8 | 0 | -8 | 2 | 10 |
| 9 | SUS position | *SUS positioning in relation to generics* | 10 | 10 | 0 | 0 | 10 |
| 10 | Public influence on sector | *Government effort (executive and legislative)* | -5 | 0 | -5 | 5 | 10 |

Source: prepared by the authors

The converging Delphi scenario revealed these expectations for each field:

1. National Generic Pharmaceutical Industry - In this respect, the result of the experts' opinion indicates that the most likely scenario is stability, which means that the national pharmaceutical industry of generics tends to remain the market share leader within the generics segment
2. Local Pharmaceutical Industry - In the opinion of experts, there is a very favorable scenario for generics to assume a greater market share in the coming years due to shortage of government budget and upcoming patent expiration.
3. Biological and Biosimilar Medicines and New Technologies - Negative point: there is a unanimous view that biosimilars will not have the same ease of entry into the market that generics had in their 10-year horizon. The main factor that supports this opinion is medical and technical: exchanging a biosimilar medicine vs. a biological reference is much more complex. Positive point: the pressure to freeze the budget

generated by PEC 241 and the potential increase in chronic biological patients tends to make SUS indicate the use of biosimilars for this group of new patients (NAIVE)

4. Market Regulatory Agencies – The experts were unanimous in their perspective regarding the SUS. Everyone believes that SUS tends to focus its purchases more and more at a lower cost. Also experts believe that there will be no changes in the way ANVISA works in relation to the approval and inspection of generic medicines.
5. Brazilian Public Health - Among the interviewees, there is an aligned concern regarding the Brazilian population growth, population aging predicted by Fiocruz and the maintenance of incidence rates of chronic diseases that create a pocket of patients that are costly to SUS. This pocket tends to increase over the 10-year horizon while public health resources will be frozen based on the 2016 budget. From a purely political point of view, a new alignment became clear: experts do not see the possibility that in a short period of time Brazil will resume a progressive agenda and with popular/protectionist caution to the least favored, strengthening the SUS.

## 4. FINAL CONSIDERATIONS

Assessing the prospects of a market segment in a country like Brazil, which has wide social inequality between social classes and a difference in accessibility to medical treatments is a highly complex process. The Brazilian generic medicine industry has been consolidated since Law 9787/1999.

These specialists composed a future scenario that reveals the guarantee of space for the generic segment in the national market, the possibility of strengthening Brazilian industry and the prospect of increasing consumption of generics, driven by PEC 241 of the spending ceiling (constitutional amendment 95), which tends to force SUS to seek alternatives for saving and maximizing the use of its increasingly scarce resources, in the face of a growing national population that is aging demographically with the increase in their outlook on life, according to reports from Fiocruz.

We understand that it will be up to the actors (governmental and industrial) to build a trajectory that will provide the evolution of the Brazilian pharmaceutical industry and meet the health needs of the population regardless of their economic class, since the right to health is part of the national constitution.

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# Appendix – Delphi Method Participants

| DELPHI METHOD PARTICIPANTS | | | | |
|---|---|---|---|---|
| # | Name | Role/Description | Segment | Company/Inst. Name |
| 1 | Rene Delsin | CEO - Brazil Affiliate | Pharmaceutical Company | Grünenthal Group |
| 2 | Robson Faria | CFO Latin America | Pharmaceutical Company | Glenmark Pharmaceutical |
| 3 | Paulo Tonnus | Former executive, pharmaceutical industry consultant | Pharmaceutical Company | Eli Lilly (former) |
| 4 | Augusto Schulze | National Market Access Manager | Pharmaceutical Company | AbbVie |
| 5 | Luciana Scaccabarozzi | Value Proposition Manager | Pharmaceutical Company | AbbVie |
| 6 | Bruno Abreu | SINDUSFARMA Director and former ANVISA President | Regulatory Agencies | SINDUSFARMA |
| 7 | Francisco Funcia | Health Economics Consultant, professor, Finance Secretary at Diadema City in Brazil | Public Health/Government | City of Diadema - Brazil |
| 8 | Dirceu Barbano | Former ANVISA president, Consultant | Agencies/Health Policy | ANVISA (former) |
| 9 | Eliane Cortez | Health Department Secretary in São Paulo | Public Health/Government | City of São Paulo - Brazil |
| 10 | Cleila Pimenta | Health Specialist at National Industrial Development Agency | Regulatory Agencies | NIDA (national industrial dev. Agency) |